

03
0014
NILLSNAPLGPQFP (Ty 57-70) (SEQ ID NO: 2) DYSYLQDSDPDSFQD (Ty 448-462)
(SEQ ID NO: 6), YSYLQDSDPDSFQD (Ty 449-462) (SEQ ID NO: 13), and
SYLQDSDPDSFQD (Ty 450-462) (SEQ ID NO: 14).

REMARKS

Applicants respectfully request entry of the instant amendment. The amendment included in this Response is provided to address the Examiner's concerns and rejections.

The information disclosure statement filed May 15, 1997 and received in the USPTO on May 19, 1997 is believed by the Examiner to fail to comply with the provisions of MPEP §609 because no copy of the references were provided. Applicants respectfully disagree with this assertion. A copy of the self-addressed return postcard, bearing a dated stamp of receipt in the USPTO on May 19, 1997, evidences receipt of, *inter alia*, 80 references. A copy of this postcard is attached as Exhibit 1. However, in the interest of facilitating prosecution of this application, applicants provide herewith courtesy copies of all 80 references filed with the USPTO on May 15, 1997.

The amendment to the specification sets forth sequence identifiers as requested by the Examiner. Hence, the amendment to the specification adds no new matter.

Claims 1-30, 56 and 61 are presently pending. Support for new claim 64 can be found in both claims 1 and 2 as originally filed and on page 5, first paragraph of the instant specification. Support for the amendment to claim 10 can be found on page 5, first

paragraph. Applicants have cancelled withdrawn claims 31-55, 57-60, 62 and 63 but expressly reserve the right to file a divisional application to this subject matter.

Claims 1-30, 56 and 61 stand rejected under 35 U.S.C. §112, first paragraph, because the specification does not reasonably provide enablement for the peptides as broadly claimed. Applicants respectfully disagree with this rejection and with the characterization of the instant invention as "protein chemistry." Applicants assert the field of the instant invention is immunology and as such fail to see the relevance of heparin binding and mitogenic activity to the instant invention. In addition, the examples set forth in the pending Official Action simply make the observation that amino acid substitutions may reduce heparin binding or mitogenic activity. However, no correlation has been made between amino acid changes and immunogenicity of a peptide and applicants are not aware of a correlation between the properties of heparin binding, mitogenicity and a peptide's immunogenicity. Hence, applicants do not see the relevance of these biological properties to the specific and distinct claimed subject matter.

The Examiner also asserts that there is a "lack of guidance, lack of examples and lack of predictability" associated with the instant invention and specification. Applicants respectfully disagree with this position. Detailed guidance can be found throughout the specification for determining amino acid substitution as numerous examples of amino acid deletions, extensions and substitutions are provided. Analogs of peptides listed as SEQ ID NOS: 1, 2, 6, 13 and 14, which incorporate conservative substitution or chemical derivatives of amino acids of these peptides are encompassed within the instant specification (page 9, lines 11-18). Examples of conservative substitutions are given, *inter alia*, on page 9, lines

25-34 and examples of chemical derivatives are given, *inter alia*, on page 10, lines 3-29.

Examples of modifications that increase immunogenicity of peptides listed as SEQ ID NOS:

1, 2, 6, 13 and 14 are given on page 10, line 30 through page 11, line 16. Examples of specific substitutions are given, *inter alia*, on page 12, line 3 through page 14, line 4.

Example II gives guidance for and examples of making amino acid substitutions to increase immunogenicity of the peptides. The teachings of favorable and unfavorable substitutions at specific positions accord a high level of predictability to this invention (see page 44, line 21 through page 45, line 25 and figures 6-12). These numerous examples provide a sufficient level of predictability to the skilled artisan to allow her to select amino acid substitutions in accordance with this invention. As the Examiner knows, every possible alternative need not be disclosed to enable the generic composition so long as sufficient guidance is provided to enable the skilled artisan to carry out the invention without undue experimentation.

Applicants respectfully assert that the instant application provides extensive -- and hence sufficient -- guidance to the skilled artisan on the selection of amino acids for the claimed peptides. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 3 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. Applicants respectfully traverse this rejection.

However, in order to expedite the prosecution of this application, claim 3 has been amended to address the Examiner's concerns. Support for the amendment to claim 3 can be found in the preamble of claim 3. Reconsideration and withdrawal of the § 112 rejection is respectfully requested.

In light of the above remarks and the amendments to the claims, Applicants assert that the claims are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited.

If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is respectfully urged to telephone the undersigned at (212) 415-8564.

AUTHORIZATION

No additional fee is believed to be necessary.

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2026-4205.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or

credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2026-4205. A DUPLICATE OF THIS SHEET IS ATTACHED.

Respectfully submitted,

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Dated: February 2, 1998

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